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EXAMINER				
CHU, KAIYEU K				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/538,425

Applicant(s)

FLORY ET AL.

Examiner

KAIYEU CHU

Art Unit

4177

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 June 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SI/08)
Paper No(s)/Mail Date 05/25/2007
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This office action is in response to the application for patent filed on 06/10/2005. Claims 1-20 are pending.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 05/25/2007 is in compliance with the provisions of 37 CFR 1.97 and is being considered by the examiner. Patents Nos. 5009227, 4986815, and 5551421 were each repeated on the IDS and the extraneous occurrences have thus been crossed out.

Drawings

2. The drawings are objected to because reference "150" in Fig. 6 should be corrected to - 150c -, references "5a" and "52" in Fig. 11 should be corrected to - 50a- and - 52a -, and reference "50" in Fig. 12 should be corrected to - 50a -, in order to correct the typographic errors.

In addition, the drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "224" has been used to designate both an alternate base in Figs. 11-12 and a different alternate base in Figs. 13-14.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure

number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claim 3 is objected to because of the following informalities: the term "comprised" in line 2 should be corrected to - comprises- -. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 14-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, there is no support in the specification or drawings for more than one first clip-retaining member and more than one second clip-retaining member. The terms "at least one first clip-retaining member" and "at least one second clip-retaining member" have enlarged the scope of the invention.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the claim language "a tube-holding assembly carried by said base, said tube-holding assembly having a tube-securing block fixed to said base and two clip-securing blocks arranged on opposite sides of said tube-securing block" (lines 3-5) is confusing because it is unclear as to whether the "two clip-securing blocks" are part of the "tube-holding assembly." In addition, the limitation "said base end portion of said clip" (line 10) lacks proper antecedent basis because the base end portion is never defined to be a part of the clip.

Regarding claim 4, the limitation "toward second each other" (line 3) is unclear. For purposes of examination, this limitation has been assumed to have the meaning: - - toward each other- -.

Regarding claim 12, the limitation "the top surface of the legs" (line 5) is inconsistent with what is shown in the drawings and described in the specification, and it is thus unclear as to what the limitation refers to. For purposes of examination, this limitation has been assumed to have the meaning: - -the top surface of the arms- -. Antecedent basis for this limitation in the claim will need to be established. In addition, Claim 12 recites the limitation "the restraining strap portions" in line 6. There is insufficient antecedent basis for this limitation in the claim.

Regarding claim 14, it is unclear as to how the "base" has "a first tube-bearing surface." Based on the specification and drawings, it does not appear that the base has a tube-bearing surface, but instead the tube-bearing surface appears to belong to the tube-holding assembly.

Claim 15 recites the limitation "said at least one second clip-retraining surface" in line 4. There is insufficient antecedent basis for this limitation in the claim. It is suggested that the limitation be corrected to - -said at least one second clip-retraining member- - in order to remedy the issue.

Claim 19 recites the limitation "first and second clip retaining members from becoming disengaged." It is unclear as to what the clip retaining members are becoming disengaged *from*.

Claims 2-3, 5-11, 13, 16-18, and 20 are also rejected as being dependent on one of the rejected claims 1 and 14.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 14 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Andrew (US Patent No. 3,602,227).

Regarding claim 14, Fig. 1 of Andrew teaches a base (14) having a first clip-retaining member (sawtoothed wall 23), a face-bearing surface (the bottom surface of the dovetail projection 14), and a first tube-bearing surface (the curved wall area connecting sawtoothed walls 22 and 23); a clip (2) having a second clip retaining member (sawtoothed wall 21) and a second tube bearing surface (the curved surface adjacent sawtoothed wall 21), and wherein the second clip-retaining member is engagable with the first clip-retaining member (see column 2, lines 23-27).

Regarding claim 19, Fig. 2 of Andrew teaches a latch element (5, 6) that prevents the first and second clip retaining members from becoming disengaged. As a result of the latch element, the clamp can only be unfastened by breaking the clamp as shown in Fig. 4 (see column 2, lines 28-30).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1, 4-5, 7-8, 10, 12-15, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dominguez (US Patent No. 6,526,978 B2) in view of Schiefer et al. (US Patent No. 4,118,838).

Regarding claim 1, Figs. 1-4 of Dominguez show an endotracheal tube holder (10) having a base (17) including a bottom surface bearing against a patient's face; a tube-holding assembly (18, 18A, 18B) having a tube-securing block (18) fixed to the base and two clip-securing blocks(18A, 18B) arranged on opposite sides of the tube-

securing block (bottom portion of right angle member 18 that connects sides 18A and 18B); and a tube-retaining clip having two legs (19) each engaging with one of the clip-securing blocks (18A, 18B), and each leg being inserted between a respective space between the tube-securing block and the respective clip-securing block (see Fig. 2).

Dominguez's tube-retaining clip differs from the present invention in that Dominguez's clip lacks a base end portion. However, Fig. 1 of Schiefer teaches a tube-holding assembly (10) having a tube-securing block (14) and two clip-securing blocks (12) arranged on opposite sides of the tube-securing block; a tube-retaining clip (20) having two legs (21) extending from a base end portion (the upper portion of the clip 20), the legs arranged to be engaged to the clip-securing blocks, each leg inserted between a respective space (any space that exists between each clip-securing block and a portion of the tube securing block) between the tube-securing block and each respective clip-securing block wherein a tube is captured between the tube-securing block and the base end portion of the clip. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the tube-holding assembly (18, 18A, 18B) and stationary clip (19) of Dominguez with the tube-holding assembly (10) and removable clip (20) as taught by Schiefer so that the clip of the endotracheal tube holder of Dominguez can be easily engaged with the clip securing blocks.

Regarding claim 4, the modified endotracheal tube holder of Dominguez teaches that the clip-securing blocks (Schiefer: 12) each comprise first teeth (Schiefer: 13) on sides of the clip-securing blocks that face toward second each other, and the legs (Schiefer: 21) comprise second teeth (Schiefer: 23) on sides of the legs facing away

from each other wherein said first and second teeth are mutually engaged wherein the clip is installed to the base (Schiefer: column 4, lines 18-22).

Regarding claim 5, the modified endotracheal tube holder of Dominguez teaches that the first and second teeth are angled in ratchet fashion to allow the clip to be installed by pushing the legs into the spaces while resisting retraction of the legs from engagement to the clip-securing blocks wherein the clip is pulled in an opposite direction (Schiefer: column 2, lines 54-61).

Regarding claim 7, the modified endotracheal tube holder of Dominguez teaches that the base (Dominguez: 17) includes arms (Dominguez: each side of chin piece 14) that straddle the patient's mouth extending in a transverse direction to the patient's face and that the tube-securing block (Schiefer: 14) is arranged adjacent to a side of the patient's mouth (see Fig. 1 of Dominguez).

Regarding claim 8, the modified endotracheal tube holder of Dominguez teaches a restraining strap (Dominguez: 12, 13) wherein the base includes an attachment (Dominguez: 15A, 16A) for the strap, wherein the strap can encircle the patient's head to hold the base to the patient's face (see Fig. 1 of Dominguez).

Regarding claim 10, the modified endotracheal tube holder of Dominguez teaches that the retaining clip is separable from the base when the legs are disengaged from the clip-securing block (see Fig. 1 of Schiefer).

Regarding claim 12, the modified endotracheal tube holder of Dominguez teaches that the strap comprises two parallel strap portions (Dominguez: 12, 13), and comprises hook and loop engagable fasteners (Dominguez: 12A, 13A) applied between

the top surface of the arms and the restraining strap portions (Dominguez: Fig. 1 shows part of the Velcro engagement occurring between the arm and the strap 13) and the strap comprises a base portion (Dominguez: the engagement between the straps 12,13 and the openings 15B, 16B shown in Fig. 2) fixed to the base. For the remaining limitations, refer to the rejection of claim 8 for reasoning.

Regarding claim 13, the modified endotracheal tube holder of Dominguez teaches that the tube-securing block (Schiefer: 14) comprises an overhang position (sides of walls 14 that are adjacent to walls 12) above each space, wherein the overhang portions retain the clip to the base to prevent separation in a direction perpendicular to a top surface of the base.

Regarding claim 14, Figs. 1-3 of Dominguez teach an endotracheal tube holder (10) with a base (17) having a face-bearing surface, a first tube-bearing surface (surface proximate the tube), and a first clip-retaining member (18); and a clip (19) having a second clip-retaining member (legs of clip 19) and a second tube-bearing surface (where the legs of clip 19 retain the tube). It is noted that Dominguez does not teach the second clip-retaining member being engagable with the first clip-retaining member when the clip is pushed onto the base in a linear direction to latch the first and second tube-bearing surfaces tightly against a tube located. However, Fig. 1 of Schiefer teaches a first clip-retaining member (10) and a clip (20) having a second clip-retaining member (21), and a second tube-bearing surface (where the clip 20 retains a tube), the second clip-retaining member engagable with the first clip-retaining member when the clip is pushed onto the base in a linear direction to latch the first and second tube-

bearing surfaces tightly against a tube located therebetween (see column 4, lines 18-22). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the first clip-retaining member and the clip of Dominguez with the first clip-retaining member and engagable clip as taught by Schiefer so that the clip of the endotracheal tube holder of Dominguez can be easily engaged with the first clip-retaining member.

Regarding claim 15, the modified endotracheal tube holder of Dominguez teaches that the first clip-retaining member comprises two clip-retaining blocks (Schiefer: 12) arranged on opposite sides of, and spaced from, the first tube-bearing surface, and the second clip-retaining member comprises two legs (Schiefer: 21), each leg engagable to a respective one clip-retaining block (Schiefer: column 3, line 64 – column 4, line 3).

Regarding claim 17, the modified endotracheal tube holder of Dominguez teaches that the base comprises spaced apart arms (Dominguez: each side of chin piece 14) for bearing on the patient's face, straddling the patient's mouth, and a base portion (Dominguez: part of base 17 that connects arm flaps of chin piece 14 together) connecting the arms and carrying the first tube-bearing surface, the first tube-bearing surface arranged to be located at a corner of the patient's mouth.

13. Claims 2-3 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dominguez in view of Schiefer as applied to claims 1, 4-5, 7-8, 10, 12-15, and 17 above, and further in view of Hayatdavoudi (US Patent No. 4,823,919).

Regarding claims 2-3 and 16, the modified endotracheal tube holder of Dominguez does not teach that each of the tube-securing block (i.e. first tube-bearing surface) and the base end portion (i.e. second tube-bearing surface) comprises a pair of planar areas of tube-engaging teeth. However, Hayatdavoudi teaches multiple sets of planar areas (see column 3, lines 30-33) of tube-engaging teeth (46) that are used to grip a tube (see column 1, lines 37-41; column 3, lines 16-21). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the tube-securing block and base end portion of the modified endotracheal tube holder of Dominguez to have multiple planar areas of tube-engaging teeth as taught by Hayatdavoudi in order to securely hold a tube in position.

14. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dominguez in view of Schiefer as applied to claims 1, 4-5, 7-8, 10, 12-15, and 17 above, and further in view of Rosenbeck (US Patent No. 3,940,823).

Regarding claim 6, the modified endotracheal tube holder of Dominguez does not teach that the legs can be squeezed together to release the first teeth from the second teeth to remove the clip from the tube-holding assembly. Instead, Schiefer teaches that the clip may be removed by using a tool such as a screwdriver to force the clip-retaining blocks to disengage from the legs of the clip (see column 4, lines 26-29). However, Rosenbeck teaches a clip with members (74, 76) that must be squeezed together in order to release the clip from the structure it is engaged to (see column 4, lines 52-57). Thus, it would have been obvious to one of ordinary skill in the art at the time the

invention was made to modify the legs of the modified endotracheal tube holder of Dominguez to be able to be squeezed together like the members on the clip of Rosenbeck, as doing so would allow the clip of Dominguez to be much more easily removed than by using its current method of using a screwdriver.

15. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dominguez in view of Schiefer as applied to claims 1, 4-5, 7-8, 10, 12-15, and 17 above, and further in view of Islava (US Patent No. 5,829,430).

Regarding claim 9, the modified endotracheal tube holder of Dominguez does not teach that the base comprises a bite block that extends below said bottom surface into the patient's mouth to prevent closing together of the patient's upper and lower teeth. However, Islava teaches an endotracheal tube holder (10) with a bite block (45) that extends below said bottom surface of a base (18) of the endotracheal tube holder into a patient's mouth to prevent closing together of the patient's upper and lower teeth. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the base of the modified endotracheal tube holder of Dominguez with a bite block that extends into a patient's mouth as taught by Islava, as doing so would help the modified endotracheal tube holder of Dominguez secure an endotracheal tube.

16. Claims 11 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dominguez in view of Schiefer as applied to claims 1, 4-5, 7-8, 10, 12-15, and 17 above, and further in view of Wing et al. (US Patent No. 6,409,220 B1) .

Regarding claims 11 and 18, the modified endotracheal tube holder of Dominguez does not teach a tether connecting the base and the clip. However, Fig. 1 of Wing teaches a tether (60) connecting a body portion (20) to a cap portion (80). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the base and the clip of the modified endotracheal tube holder of Dominguez to have a tether connecting the two elements together as taught by Wing, as doing so would help prevent loss or misplacement of either the clip or the base.

17. Claims 14 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dominguez in view of Young, Jr., et al (US Patent No. 2,534,690).

Regarding claim 14, Figs. 1-3 of Dominguez teach an endotracheal tube holder (10) with a base (17) having a face-bearing surface and a first tube-bearing surface (surface proximate the tube). Although Dominguez teaches a sort of first clip-retaining member (18, 18A, 18B), it is noted that Dominguez does not necessarily teach the claimed first clip-retaining member or the clip. However, Figs. 1-2 of Young teaches a first clip-retaining member (10) and a clip (40) having at least one second clip-retaining member (48, 49), and a second tube-bearing surface, the second clip-retaining member engagable with the first clip-retaining member when the clip is pushed onto the base in

a linear direction to latch the first and second tube-bearing surfaces tightly against a tube located therebetween (see column 2, lines 42-45). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the clip-retaining member of Dominguez with the clip-retaining member and the clip of Young in order to provide the endotracheal tube holder of Dominguez with an alternative method of holding an endotracheal tube.

Regarding claims 19 and 20, Figs. 1-2 of Young show that the modified endotracheal tube holder of Dominguez teaches that the first clip-retaining member comprises two clip-retaining blocks (14, 15) arranged on opposite sides of, and spaced from, the first tube-bearing surface, and the second clip-retaining member comprises two legs (48, 49), each leg engagable to a respective one clip-retaining block (see column 4, lines 11-15); and at least one latch element (44, 45) for engaging with notches (16, 17) and that is manually movable and arranged to brace between the first leg (48) and the second leg (49) to prevent disengagement of the legs and the clip-retaining blocks.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Riley et al. (US Patent No. 5,775,778) teaches a saw-toothed engagement that may be disengaged by squeezing the arms on one of the engagement members. Freed (US Patent No. 6,029,668) teaches an endotracheal tube holder with safety and securing clamps. Wilderman (US Patent No. 4,202,087) teaches a saw-

toothed chip engagement for retaining cables. Tucker (US Patent No. 5,342,324) teaches a clip device for holding a flexible tube carrying a needle. Ismert (US Patent No. 6,126,122) teaches a pipe clamp using a saw-toothed engagement. Mizusawa (US Patent No. 3,894,706) teaches a tubing clamp with gripper means and latching means to insure continued engagement with clamped tubes by the gripper means. Wollar (US Patent No. 4,936,530) teaches a releasable clip for holding an elongated member with multiple latch means.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAIYEU CHU whose telephone number is (571)270-5376. The examiner can normally be reached on Monday-Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine R. Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KAIYEU CHU/
Examiner, Art Unit 3771
04/07/2010

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